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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,597	12/19/2000	Bruce J. Barclay	VASC 1020-1	3762

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/740,597	BARCLAY ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-38* is/are pending in the application.

4a) Of the above claim(s) *37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 2/4/05 has now been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that various drugs are disclosed in paragraph 44 of the specification, but nowhere does the disclosure suggest the use of two different drugs. Additionally, throughout the specification the single term drug is used and does use plural terminology.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28,29,32,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. (6355055) in view of Kropf '849. Waksman et al. show (Fig. 1) a coiled stent body **12** (col. 2, line 60) covered by a porous graft material **20** extending along the coil path. Fig. 2 shows a therapeutic agent **40** is between the inner and outer wall of graft material and Waksman discloses the agent can be NO, col. 4, lines 3,15,22. Figs. 4A-4D show there is a protective layer **50** that is degradable (col. 4, lines 46-50). Waksman also discloses the body or core coil is made of metal, col. 6, lines 33-34. NO generators are well known in the art as common vasodilators. Waksman discloses that the stent is delivered inside a vessel of a patient, col. 3, lines 5-7. Waksman et al. additionally disclose the graft material promotes tissue ingrowth, col. 3, lines 22-25. However, Waksman fails to disclose the coil as having spaced apart parallel side elements joined by connector elements. Kropf teaches a coiled stent (Fig. 5) spaced apart parallel side elements joined by connector elements. Kropf teaches that the structural design enables tissue ingrowth to occur and thus provides an excellent scaffold, col. 4, lines 6-8. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the stent of Waksman et al. in order to provide a stent with a larger scaffold for tissue ingrowth to adhere to.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. '055 in view of Kropf '849 as applied to claim 28 above, and further in view of Razavi (5676685). Waksman et al. as modified by Kropf is explained supra. However, Waksman in view of Kropf fail to disclose the metal for the coil being nickel-titanium. Razavi also discloses the body or core coil is made of metal, such as NiTi (col. 2, lines 37-44). It would have been obvious to one of ordinary skill in the art to modify the material used for the coil as taught by Razavi in the stent of Waksman as modified by Kropf in order to provide a self-expanding coil and temperature responsive.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. '055 in view of Kropf '849 as applied to claim 28 above, and further in view of Herzog et al. (WO 98/08482). Waksman et al. as modified by Kropf is explained supra. However, Waksman in view of Kropf fail to disclose the drug being encapsulated. Herzog teaches the agent can also be encapsulated, page 12, line 11. It would have been obvious to one of ordinary skill in the art to modify the means of delivering the drug and encapsulating it as taught by Herzog in the stent of Waksman as modified by Kropf in order to provide a more controlled release of the NO.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. '055 in view of Kropf '849 as applied to claim 28 above, and further in view of Ragheb et al. (5873904). Waksman et al. as modified by Kropf is explained supra. However, Waksman et al. in view of Kropf fail to disclose a second drug being used in conjunction with the NO generator. Ragheb teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been

obvious to one of ordinary skill in the art to use a second agent as taught by Ragheb with the stent of Razavi as modified by Kropf in order to provide a greater therapeutic medical device with multiple treatment capabilities.

Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. (5824054) in view of Herzog et al. (WO 98/08482). Khosravi et al. disclose (Fig. 1) a prosthesis with a coiled body **11** with a coiled sleeve **12** extending along the coiled body. Fig. 8B shows the coiled body has spaced apart parallel side elements joined by connector elements. Khosravi also discloses the sleeve material is made of PTFE, col. 5, lines 9,10. The coiled body can be made of metal, i.e. nickel-titanium col. 3, lines 24-26. Khosravi additionally discloses the sleeve material sandwiching the coiled body is porous, col. 4, lines 63-67 and col. 5, lines 1-6,15-17. Khosravi does disclose a bioactive agent or drug can be included in the graft material, col. 4, line 65. Fig. 8A shows a stent body with a helical fashion and Khosravi also discloses various forms or modifications can be made to the body design, col. 10, lines 56-62. However, Khosravi et al. fail to disclose drug used to be a NO generator or that a delay release material is in the form of encapsulation. Herzog et al. teach a stent with a sleeve or coating having an interior surface that houses the stent, and a NO generator within the sleeve interior, page 6, lines 7,8, page 14, lines 20-32. Herzog teaches the agent can also be encapsulated, page 12, line 11. It would have been obvious to one of ordinary skill in the art to modify the drug used or to encapsulate the drug as taught by Herzog with the stent of Khosravi to inhibit restenosis and control its occurrence.

Response to Arguments

Applicant's arguments with respect to claim 28 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino